

Application No.: 10/723,947

7

Docket No.: 514112000320

REMARKS

Upon entry of this amendment, claims 1-27 and 36-37 are pending. Claims 1, 11-13, 19, 21, 23 and 36 have been amended. Claim 37 has been added. No new matter was added by this amendment. Claims 28-35 have been canceled without prejudice subsequent revival. The Applicants reserve the right to prosecute the canceled claims in a divisional application. Entry of this amendment is respectfully requested.

The Amendment

In order to expedite prosecution of the application and advance the case toward allowance, the specification and claims have been amended. More specifically, the specification has been amended to correct the reference to Figure legends and to remove an embedded hyper link.

Claim 1 has been amended to specify that the isolated nucleic acid encodes a barley or wheat ZCCT1 polypeptide. Support for this amendment can be found throughout the specification and, for example, on pages 12-13; page 24, third paragraph; pages 25-37; and page 38, second paragraph, lines 7-12.

Claims 11-13 have amended to specify that the cell comprising the vector is an isolated cell. Support for this amendment can be found, for example, on page 20, fourth paragraph.

Claims 19-23 have been amended to clarify that the seed comprising the nucleic acid is transgenic. Support for this amendment can be found, for example, on page 21, last paragraph; page 22, first paragraph; page 42; page 43, second paragraph; and page 83, first paragraph.

Claim 36 has been amended to clarify that the wheat polypeptide is encoded by the nucleic acid selected from the group consisting of SEQ ID NO: 75, SEQ ID NO: 79, SEQ ID NO: 82 and SEQ ID NO: 85. Support for this amendment can be found, for example, on pages 27-34.

New claim 37 indicates that the barley polypeptide is encoded by SEQ ID NO: 88 or SEQ ID NO: 91. Support for this amendment can be found, for example, on pages 35-37.

Information Disclosure Statement (IDS)

The Examiner indicated that the recitation "International Search Report" [in the IDS] is not appropriate for printing on a patent. Hence, only the titles of the International Search Report

Application No.: 10/723,947

8

Docket No.: 514112000320

have been considered. The reference to *International Search Report* in the IDS filed on September 21, 2005 was provided to the Examiner so that he could see when Applicants received the Search Report. The references in the Search report were provided to the Examiner with the IDS.

Brief Description of the Drawings

The Examiner has requested correction of the specification because the drawings are not referred to properly. The specification has been amended accordingly (see *Amendment to the Specification* beginning on page 2, *supra*).

Specification

The specification is objected to because it contains an embedded hyperlink on page 81. The specification has been amended to remove the hyperlink.

Rejection Under 35 U.S.C. §112

Claims 1-27 and 34-35 are rejected under 35 U.S.C. §112, first paragraph, as allegedly lacking written description. Specifically, the Office Action asserts that the Applicants do not describe any polynucleotide sequences that encode a protein "having at least 90% identity to the polypeptide encoded by SEQ ID NO: 75."

The claims have been amended to remove any reference to sequence identity. However, this amendment was made to advance prosecution toward allowance and must not be interpreted as acquiescence in the rejection. The amended claims are now drawn to "an isolated nucleic acid that encodes a barley or wheat ZCCT1 polypeptide." Written support for this amendment can be found, for example, on pages 12-13; on page 24, third paragraph; on pages 25-37; and on page 38, second paragraph, lines 7-12. Claims 34-35 have been canceled.

Thus, this rejection is moot.

It is further stated for the record that the specification provides a clear definition of what a ZCCT1 protein is (see page 4 of the specification) and the sequences of ZCCT1 proteins from wheat and barley are disclosed. For example, the *T. Monococcum* ZCCT1 gene was cloned and its polypeptide sequence is shown on page 28 of the specification (*i.e.*, two alleles, see SEQ ID

Application No.: 10/723,947

9

Docket No.: 514112000320

NOS: 76 and 77). In addition, the polypeptide sequence from Langdon (tetraploid wheat) is shown on page 29 (see SEQ ID NO: 80); and the polypeptide sequences from barley, *i.e.*, *Dairokkaku* ZCCT-46 (Ha and Hb) are shown on page 35 (SEQ ID NO: 88) and page 37 (see SEQ ID NO: 92), respectively. Even in *University of California v. Eli Lilly & Co.*, the Court of Appeals for the Federal Circuit stated that a written description for a chemical genus "requires a precise definition, such as by structure, formula, chemical name or physical properties."¹ [Emphasis added.] As shown above, the application teaches several structures of nucleic acid and polypeptide sequences of ZCCT1 proteins that fall within the scope of the claimed genus. Thus, the Applicants were clearly in possession of "an isolated nucleic acid that encodes a barley or wheat ZCCT1 polypeptide" at the time of the invention.

Claims 1-27 and 34-36 are rejected under 35 U.S.C. §112, first paragraph, as allegedly lacking enablement. The Office Action contends that one of skill in the art cannot predict which nucleic acid that encodes a protein having at least 90% sequence identity to the polypeptide encoded by SEQ ID NO: 75, will encode a protein with the same activity.

To the extent that the rejection applies to the claims as amended it is respectfully traverse.

As indicated above, the claims have been amended to remove any reference to sequence identity. The amended claims are now drawn to "an isolated nucleic acid that encodes a barley or wheat ZCCT1 polypeptide." As such, the claims are fully enabled.

The Office Action alleges that: "Applicants have not reduced to practice the invention...Applicants have not transformed a wild-type plant with any of the claimed sequences such that the introduced sequence is ectopically expressed to produce a plant with an altered vernalization phenotype." To the contrary, pages 81-83 of the specification relate to the generation of recombinant ZCCT1 plasmids and transformation of 45 Jagger wheat plants. The resulting *transgenic* wheat plants showed a definite acceleration in flowering time compared to controls. **In fact, all plants carrying the transgene flowered 3-5 weeks earlier compared to the 11 plants that were homozygous for the absence of the transgene.** These experiments confirmed that

¹ *University of California v. Eli Lilly & Co.*, 43 USPQ2d at 1405.

Application No.: 10/723,947

10

Docket No.: 514112000320

reduction of the mRNA level of ZCCT1 in wheat results in the acceleration of flowering time, thereby altering the plant's response to vernalization.

As the Examiner can see, the specification provides nucleic acid and protein sequences for wheat and barley ZCCT1 proteins (*supra*). The Applicants have taught how to produce the recombinant ZCCT1 plasmid (page 81, last paragraph); how to transform immature plant embryos with the recombinant plasmid (page 81, last paragraph); how to test the transcription level of the expressed ZCCT1 protein via the TaqMan® system (page 82, third paragraph); how to determine the transgene in 45 plants from the T1 progeny by Southern blots (page 82, last paragraph); and, finally, how to confirm that all plants carrying the transgene flower earlier than control plants (page 83, first paragraph). Notably, the Applicants also cloned and sequenced two ZCCT genes from winter barley *Dairokkaku* (see page 80, fifth paragraph). Thus, it would be merely routine for one of skill in the art to follow the Applicants' teachings of expressing a ZCCT1 protein in a wheat plant and apply the same strategy to other wheat plants or barely plants. The Examiner is reminded that a "considerable amount of experimentation is permissible, if it is merely routine, or if the specification in question provides a reasonable amount of guidance with respect to the direction in which experimentation should precede."² Besides, "[The] fact that experimentation may be complex does not necessarily make it undue, if the art typically engages in such experimentation."³ In light of the above, the claims are believed to be fully enabled and Applicants respectfully request that the rejection of claims 1-27 and 36 under 35 U.S.C. §112, first paragraph, be withdrawn.

Rejection Under 35 U.S.C. §112

Claims 19, 21 and 23 are rejected under 35 U.S.C. §101, as allegedly being directed to non-statutory subject matter. However, the Examiner has indicated that the amendment of the claims to recite that the seeds comprise the construct that was introduced into the parent would overcome the rejection. The Applicants gratefully acknowledge the Examiner's suggestion and

² *Wands*, 8 USPQ2d at 1404 (quoting *In re Jackson*, 217 USPQ 804 (Bd. Pat. App. & Int. 1982)).

³ *In re Certain Limited -- Charge Cell Culture Microcarriers*, 221 USPQ 1165, 1174 (Int'l Trade Comm'n 1983), *aff'd*, sub nom., *Massachusetts Institute of Technology v. A. B. Fortia*, 774 F.2d 1104, 227 USPQ 428 (Fed. Cir. 1985).

Application No.: 10/723,947

11

Docket No.: 514112000320

have amended the claim accordingly. The claims are now drawn to transgenic seed comprising the nucleic acid of the appropriate preceding claim. Thus, the rejections should be moot.

The Examiner further rejected claims 11-13 under 35 U.S.C. §101, as allegedly being directed to non-statutory subject matter. However, the Examiner indicated that amending the claims to recite "[An] isolated cell" would obviate the rejection. Again, the Applicants gratefully acknowledge the Examiner's suggestion and have amended claim 11-13 to be drawn to "an isolated cell." Thus, the rejection should be moot.

CONCLUSION

In view of the above, each of the presently pending claims in this application is believed to be in immediate condition for allowance. Accordingly, the Examiner is respectfully requested to withdraw the outstanding rejection of the claims and to pass this application to issue. If it is determined that a telephone conference would expedite the prosecution of this application, the Examiner is invited to telephone the undersigned at the number given below.

In the event the U.S. Patent and Trademark office determines that an extension and/or other relief is required, applicant petitions for any required relief including extensions of time and authorizes the Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to Deposit Account No. 03-1952 referencing docket no. 514112000320. However, the Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

Dated: July 25, 2006

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SF-2161712

Application No.: 10/723,947

12

Docket No.: 514112000320

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